REMARKS

This is in response to the Office Action mailed April 14, 2006 for the above-captioned application. Reconsideration is respectfully requested.

Non-elected claim 13 has been canceled without prejudice.

The Examiner has maintained the objection to claims 3, 6 and 9 as containing improper Markush groups based on the prior characterization of the different sequences as separate inventions, rather than species. It is pointed out that generic (or linking) claims exist in this application. Furthermore, Applicants direct the Examiner's attention to MPEP § 803.02 relating to Markush groups in method claims. As observed there,

> when the Markush group occurs in a claim reciting a process or a combination (not a single compound), it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly responsible for their function in the claimed relationship, and it is clear from their very nature or from the prior art that all of them possess this property.

Here, the common property is recited in the claims, namely all of the compounds are effective to reduce the amount of clusterin. Accordingly, Applicants again submit that the restriction in this case should be treated only as a species election.

Claim 14 has been added. Claim 14 specifically defines the therapeutic agent as an oligonucleotide therapeutic. The remaining claims other than claim 1 have been amended such that they are ultimately dependent on added claim 14. Claim 1 remains generic relative to claim 14.

Claims 1-10 were rejected as indefinite because the Examiner asserted that the term "effective amount of clusterin" is indefinite. Claim 1 has been amended to delete the term "effective" from the claim. This is believed to be fully responsive to and to overcome the rejection of claim 1. Further, added independent claim 14 is comparable to amended claim 1 in this respect. Thus the rejection of the other claims is also rendered moot.

Claim 1 stands rejected under 35 USC § 112, first paragraph for failure to comply with the written description requirement. The basis for the rejection is the fact that claim 1 is not limited to a particular type of therapeutic agent, and that the application only discloses specific examples of antisense oligonucleotide and RNAi inhibitors, and that there are other general types of inhibitors that could be used within the scope of the claim that are not specifically named. Applicants respectfully traverse this rejection.

As a first matter, Applicants note that the Examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). Instead, the examiner has said that the person skilled in the art could not envisage the scope of the therapeutic agents. Applicants submit that these are two very different standards, and that the Examiner has failed to supply reasoning for the one that, by law, matters. Method claims routinely contain limitations to steps such as "measuring the amount of X" without disclosing every possible way of making the measurement or allowing the person skill in the art to "envisage" every possible way. Here, Applicants invention is a method of treating melanoma using agents that reduce the amount of clusterin. The Examiner has offered no reasons why a person skilled in the art would not recognize this scope of invention in the specification, and therefore has not met the initial burden for a rejection for lack of written description.

It is further noted that the Examiner's explanation of the rejection focuses on one aspect of the claim, rather than on the claimed invention as a whole. The Court of Appeals for the Federal Circuit has repeatedly noted the importance of looking at the invention when considering a written description issue. *Moba B.V. v. Diamond Automation Inc.*, 325 F.3d 1306, 1320, 66 USPQ2d 1429, 1439 (Fed. Cir. 2003)("the test for compliance with §112 has always required sufficient information in the original disclosure to show that the inventor possessed the invention at the time of the original filing"; *Vas-Cath, Inc. v. Mahurkar*, 935 F. 2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)("the applicant must . . . convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is for purposes of the 'written description' inquiry, whatever is now claimed."); *Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000) ("The written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed'").

Consideration of In re Fuetterer, 319 F.2d 259, 138 USPQ 217 (CCPA 1963) also demonstrates the importance of focusing on the invention as claimed. The claims in Fuetterer referred to a rubber stock composition useful in producing tire treads and included a functional recitation of "an inorganic salt capable" of maintaining an homogeneous distribution of another component in the composition. The disclosure listed the function desired and four members of the class having that function. The CCPA found that this claim met the requirements of 35 U.S.C. § 112, first paragraph, stating that:

> Appellant's invention is the combination claimed and not the discovery that certain inorganic salts have colloid suspending properties. We see nothing in patent law which requires appellant to discover which of all those salts have such

> properties and which will function properly in his combination. The invention description clearly indicates that any inorganic salt which has such properties is usable in his combination. If others in the future discover what inorganic salts additional to those enumerated do have such properties, it is clear appellant will have no control over them per se, and equally clear his claims should not be so restricted that they can be avoided merely by using some inorganic salt not named by appellant in his disclosure.

319 F.2d at 265, 138 USPQ at 223. This case is directly on point, and clearly demonstrates the error of the rejection.

Applicants' invention is not the therapeutic agent that reduces the amount of clusterin *per se*. Appellants' invention is a method for treating melanoma by using such an agent to reduce the amount of clusterin. Applying the logic of *Fuetterer*, if others in the future discover therapeutic agents additional to those enumerated that have such properties of reducing clusterin, it is clear applicants will have no control over them *per se*, and equally clear the present claims should not be so restricted that they can be avoided merely by using some therapeutic agent not named by applicant in the present disclosure. Since this is exactly what the rejection seeks to do, it is plainly in error and should be withdrawn.

For the foregoing reasons, Applicants submit that this application is in form for allowance. Favorable reconsideration and allowance of all claims, including those withdrawn as a result of the restriction requirement are respectfully urged.

Respectfully submitted,

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